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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

[Docket No. 2003N–0455]

Training Program for Regulatory Project Managers; Information Available to Industry

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER) is announcing the continuation of the Regulatory Project Management Site Tours and Regulatory Interaction Program. This training program was initiated in 1999, and it is intended to give CDER regulatory project managers an opportunity to tour pharmaceutical facilities and to exchange regulatory experiences with their industry counterparts. The Site Tours Program is intended to enhance review efficiency and quality by providing CDER staff with a better understanding of the pharmaceutical industry and its operations. Further, this program is intended to improve communication and cooperation between CDER staff and industry. The purpose of this notice is to invite pharmaceutical companies interested in participating in these programs to contact CDER.

DATES: Pharmaceutical companies may submit proposed agendas to the agency on or before [*insert date 60 days after date of publication in the* **Federal Register**].

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FOR FURTHER INFORMATION CONTACT: Patricia A. Stewart, Center for Drug Evaluation and Research (HFD–160), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7496, FAX 301–480–6036.

SUPPLEMENTARY INFORMATION:

I. Background

An important part of CDER's commitment to make safe and effective drugs available to all Americans is optimizing the efficiency and quality of the drug review process. To support this primary goal, the center has initiated various training and development programs to promote high performance of its regulatory project management staff. CDER seeks to significantly enhance review efficiency and review quality by providing the staff with a better understanding of the pharmaceutical industry and its operations. To this end, CDER is continuing this training program to give regulatory project managers the opportunity to tour pharmaceutical facilities. The goals are to provide: (1) First hand exposure to industry's drug development processes, and (2) a venue for sharing information about project management procedures (but not drug-specific information) with industry representatives.

II. Regulatory Project Management Site Tours and Regulatory Interaction Program

In this program, over a 2- to 3-day period, small groups (five or less) of regulatory project managers, accompanied by a senior level regulatory project manager, may observe operations of pharmaceutical manufacturing, packaging facilities, pathology/toxicology laboratories, and regulatory affairs operations. Neither this tour nor any part of the program is intended as a mechanism to inspect, assess, judge, or perform a regulatory function, but is meant rather to improve mutual understanding and to provide an avenue for open dialogue. During the Site Tours Program, regulatory project managers will also

participate in daily workshops with their industry counterparts, focusing on selective regulatory issues important to both CDER staff and industry. The primary objective of the daily workshops is to learn about the team approach to drug development, including drug discovery, preclinical evaluation, project tracking mechanisms, and regulatory submission operations.

The overall benefit to regulatory project managers will be exposure to project management team techniques and processes employed by the pharmaceutical industry. By participating in this program, the regulatory project manager will grow professionally by gaining a better understanding of industry processes and procedures.

III. Site Selection

All travel expenses associated with the site tours will be the responsibility of CDER, therefore, selection will be based on the availability of funds and resources for each fiscal year.

If your firm is interested in offering a site tour or learning more about this training opportunity, please respond within 60 days of this notice by submitting a proposed agenda to Patricia A. Stewart (see **FOR FURTHER INFORMATION CONTACT**).

Dated: 10/14/03

October 14, 2003.

Jeffrey Shuren,
Assistant Commissioner for Policy.

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